

Please type a plus sign (+) inside this box → +

**TRANSMITTAL  
FORM***(to be used for all correspondence after initial filing)*

Application Number	10/509,252
Filing Date	September 28, 2004
Inventor(s)	Shunichi KURODA et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	12480-000069/US

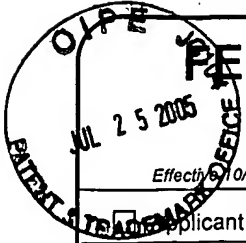
**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form  <input checked="" type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input checked="" type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application)  <input type="checkbox"/> Letter to the Official Draftsperson and ____ Sheets of Formal Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) ____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> LETTER SUBMITTING APPEAL BRIEF AND APPEAL BRIEF (w/clean version of pending claims)  <input type="checkbox"/> Appeal Communication to Group (Notice of Appeal, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  <b>Declaration</b>		
<table border="1"><tr><td>Remarks</td><td></td></tr></table>			Remarks	
Remarks				

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Harness, Dickey & Pierce, P.L.C.	Attorney Name Gregory P. Brummett	Reg. No. 41,646
Signature			
Date	July 25, 2005		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 130

Complete if Known

Application Number 10/509,522 10/509,252  
Filing Date September 28, 2004  
First Named Inventor Shunichi KURODA et al.  
Examiner Name Unassigned  
Art Unit Unassigned  
Attorney Docket No. 12480-000069/us

VI Corrected

## METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money ☐ Other ☐ None  
Order

☒ Deposit Account:

Deposit Account Number 08-0750

Deposit Account Name Harness, Dickey & Pierce, PLC

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments  
☒ Charge any additional fee(s) during the pendency of this application  
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1011	300	2011	150	Utility filing fee	
1012	200	2012	100	Design filing fee	
1013	200	2013	100	Plant filing fee	
1014	300	2014	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	
SUBTOTAL (1)					(\$ 0)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		-20 **	=	0	X		=	0
Independent Claims		-3 **	=	0	X		=	0
Multiple Dependent			=				=	0

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	50	2202	25	Claims in excess of 20	
1201	200	2201	100	Independent claims in excess of 3	
1203	360	2203	180	Multiple dependent claim, if not paid	
1204	200	2204	100	** Reissue independent claims over original patent	
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$ 0)

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	130
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1000	2403	500	Request for oral hearing	
1452	500	2452	250	Petition to revive - unavoidable	
1453	1500	2453	750	Petition to revive - unintentional	
1501	1400	2501	700	Utility issue fee (or reissue)	
1502	800	2502	400	Design issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt.	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	130.00
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$130)

### 4. SEARCH/EXAMINATION FEES

1111	500	2111	250	Utility Search Fee	
1112	100	2112	50	Design Search Fee	
1113	300	2113	150	Plant Search Fee	
1114	500	2114	250	Reissue Search Fee	
1311	200	2311	100	Utility Examination Fee	
1312	130	2312	65	Design Examination Fee	
1313	160	2313	80	Plant Examination Fee	
1314	600	2314	300	Reissue Examination Fee	
SUBTOTAL (4)					(\$0)

## SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Gregory P. Brummett	Registration No. (Attorney/Agent)	41,646	Telephone	703-668-8000
Signature	<i>Gregory P. Brummett</i>	Date	July 25, 2005		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Rec'd PCT/TO

#5  
25 JUL 2005

M/S PCT  
Attorney Docket No. 12480-000069/US

**IN THE U.S. PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Shunichi **KURODA** et al. CONF. NO.: 1324  
APPL NO.: 10/509,252 FILED: September 28, 2004  
INT'L APPL.: PCT/JP03/02600 FILED: March 5, 2003  
ENTITLED: **DRUGS FOR TREATING HEPATIC DISEASES WITH THE  
USE OF HOLLOW PROTEIN NANOPARTICLES**

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS  
UNDER 35 U.S.C. § 371**

July 25, 2005

M/S PCT  
Commissioner for Patents  
Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. § 371 in the United States Designated/Elected Office (DO/EO/US) ("Notice") dated May 25, 2005 for the above-identified patent application, please consider the remarks below.

Under the provisions of 37 C.F.R. § 1.494 or 37 C.F.R. § 1.495, attached hereto are the following additional items necessary for entering the national phase in connection with the above-identified PCT international application.

- ☒ Executed Declaration and Power of Attorney (photocopy).
- ☒ Attached is a copy of Form PCT/DO/EO/905.

## REMARKS

Favorable reconsideration of this application in light of the following remarks is respectfully requested.

No claims having been cancelled or added, the Applicants respectfully submit that claims 1-7 remain properly under consideration in this application.

### Sequence Listing(s)

It is asserted that the “application clearly fails to comply with the requirements” of 37 C.F.R. § 1.821 *et seq.* Notice at page 2. The Applicants respectfully traverse this assertion.

The Applicants note that the requirements of 37 C.F.R. § 1.821 *et seq.* are implicated only where the specification, claims and/or drawings include:

(a) Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an ***unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. . . .***

\* \* \*

(b) ***Patent applications which contain disclosures of nucleotide and/or amino acid sequences, in accordance with the definition in paragraph (a) of this section,*** shall, with regard to the manner in which the nucleotide and/or amino acid sequences are presented and described, conform exclusively to the requirements of §§ 1.821 through 1.825.

37 C.F.R. § 1.821(a)-(b) (emphasis added).

The Applicants respectfully submit that the present application includes ***no such disclosure of sequences of amino acids or nucleotides*** and is not, therefore, subject to

the requirements of 37 C.F.R. § 1.821 *et seq.* The Applicants' representative also contacted the USPTO sequence help desk to confirm the understanding that a reference to or an identification of a "gene" or a "protein" does not trigger a requirement that a corresponding nucleotide sequence or amino acid sequence be generated and provided.

The Applicants' respectfully maintain, therefore, that no Sequence Listing is required for this application and request that this requirement be withdrawn.

### CONCLUSION

In view of the above remarks, the Applicants respectfully submit that each of the requirements identified in the Notice has been addressed and either satisfied or overcome, leaving the present application in condition for allowance. A notice to that effect is respectfully requested.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

The Applicants submit that no extension fee is required because the undersigned has filed the documents within the allotted time given by the Notification of Missing Requirements (Form PCT/DO/EO/905). However, if for some reason it is determined that an extension of time is necessary, applicant hereby respectfully petitions for an appropriate extension of time for the timely filing of the present paper in accordance with the provisions of 37 C.F.R. § 1.136 and 37 C.F.R. § 1.17.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge any underpayment or non-payment of any fees required under 37


C.F.R. §§ 1.16 or 1.17, or credit any overpayment of such fees, to Deposit Account

No. 08-0750, including, in particular, extension of time fees.

☒ A check in the amount of \$130.00 is attached hereto to cover the increase  
in fees of the filing Surcharge is enclosed.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

By:  (41,646)  
Donald J. Daley  
Reg. No. 34,313

P.O. Box 8910  
Reston, VA 20195  
(703) 668-8000

DJD/GPB



## UNITED STATES PATENT AND TRADEMARK OFFICE

Rec'd PCT/PTO

25 JUL 2005

Page 1 of 3

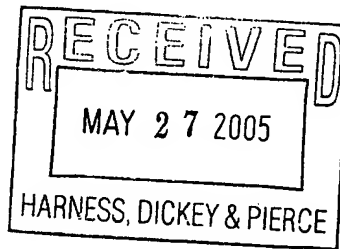
#7  
DOD/  
GPBUNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/509,252	Shunichi Kuroda	12480-000069/US

INTERNATIONAL APPLICATION NO.

PCT/JP03/02600

I.A. FILING DATE	PRIORITY DATE
03/05/2003	03/29/2002

30593  
HARNES, DICKEY & PIERCE, P.L.C.  
P.O. BOX 8910  
RESTON, VA 20195CONFIRMATION NO. 1324  
371 FORMALITIES LETTER

\*OC000000016087352\*

Date Mailed: 05/25/2005

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 09/28/2004
- English Translation of the IA filed on 09/28/2004
- Copy of the International Search Report filed on 09/28/2004
- Copy of IPE Report filed on 09/28/2004
- Preliminary Amendments filed on 09/28/2004
- Information Disclosure Statements filed on 09/28/2004
- Oath or Declaration filed on 09/28/2004
- Request for Immediate Examination filed on 09/28/2004
- Copy of references cited in ISR filed on 09/28/2004
- U.S. Basic National Fees filed on 09/28/2004
- Assignment filed on 09/28/2004
- Priority Documents filed on 09/28/2004
- Power of Attorney filed on 09/28/2004

Miss Requirements  
7/25/05 ✓ [Signature]

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - Applicant has submitted five different declarations. Each declaration executed by an inventor must include a complete listing of all inventors. The declarations submitted are not in compliance with 37 CFR 1.497(a)(3) in that each inventor is not properly identified.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR

1.492(e) is required.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$130** for a Large Entity:

- **\$130** Late oath or declaration Surcharge.
- This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217



## PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/509,252	PCT/JP03/02600	12480-000069/US

FORM PCT/DO/EO/905 (371 Formalities Notice)